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THE GENE PATENTING CONTROVERSY: A CONVERGENCE OF LAW, ECONOMIC INTERESTS, AND ETHICS*

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INTRODUCTION

One of the most controversial issues in biotechnology in the United States and Europe has been the patenting of human DNA sequences and human genes. The medical, pharmaceutical, and economic interests at stake are huge, making investments in biotechnology firms involved in gene patenting highly volatile. President Bill Clinton and Prime Minister Tony Blair recently applauded the commitment by scientists "to release raw fundamental information about the human DNA sequence and its variants rapidly into the public domain."[1] Investors, taking the communiqué as a declaration against gene patenting, sold off biotechnology shares as though they were post-Bolshevik Russian bonds.[2]

This Article will examine first how and why gene patenting became controversial, showing that the disputes are partly familiar to the extent that they are contests of political

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[1] Declan Butler, *US/UK Statement on Genome Data Prompts Debate on "Free Access,"* 404 NATURE 324 (2000).

[2] For example, the closing price of Human Genome Sciences on Friday, March 10, 2000 was $172 ½ per share. N.Y. TIMES, Mar. 14, 2000, at C25. On March 14, 2000, the stock closed at 123^{25/64}$ per share. N.Y. TIMES, Mar. 15, 2000, at C22. Celera Genomics Group closed at $202 1/8 on March 10, 2000 and at $155 on March 14, 2000. CBS MarketWatch, *at* http://cbs.marketwatch.com. *See generally* Alex Berenson & Nicholas Wade, *A Call for Sharing of Research Causes Gene Stocks to Plunge*, N.Y. TIMES, Mar. 15, 2000, at A1.

economy among individuals, companies, and governments over what constitutes allowable intellectual property rights. But this Article will then show that the contest has raised issues that have been, for the most part, historically unfamiliar in patent policy—ethics. The controversy over gene patenting has swirled most turbulently around the claim that granting private intellectual property rights in parts of the human genome violates a moral code because the genome, the common program for human life, belongs to us all.

I. BACKGROUND: THE PATENTING OF LIFE

The patenting of life was first formally contested in the United States when the case of *Diamond v. Chakrabarty*[3] made its way to the U.S. Supreme Court.[4] The case had been brought by Ananda Chakrabarty against the U.S. Patent Office after it denied him a patent on a bacterium that he had engineered to consume hydrocarbons.[5] The Patent Office argued that no patent could be issued on a living organism because it was a product of nature.[6] But in 1980, the Court held, by the slim margin of five to four, that whether the invention was alive or dead was irrelevant, that the bacterium was not a product of nature, that it was a product of Chakrabarty, and hence deserved a patent.[7]

After the *Chakrabarty* ruling, several critics insisted that the decision appeared to leave no legal obstacle to the patenting of higher forms of life—such as plants, animals, and possibly human beings—or, by implication, to the genetic engineering of such life forms.[8] In fact, although the Patent Office later held that human beings could not be patented,[9] American patents were awarded during the 1980s on a plant

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[3] 447 U.S. 303, 305-18 (1980).

[4] Daniel J. Kevles, *Ananda Chakrabarty Wins a Patent: Biotechnology, Law, and Society, 1972-1980,* 25 HIST. STUD. IN THE PHYSICAL & BIOL. SCIS. 111, 111-36 (1994).

[5] *Id.*

[6] *Id.*

[7] *Id.*

[8] Daniel J. Kevles, Diamond v. Chakrabarty *and Beyond: The Political Economy of Patenting Life, in* PRIVATE SCIENCE: BIOTECHNOLOGY AND THE RISE OF THE MOLECULAR SCIENCES 65, 65-79 (Arnold Thackray ed., 1998).

[9] *Id.*

and a mouse.[10] Patents were also allowed on human genes with a known function—for example, the gene for insulin—in a form that did not occur naturally but that had been derived from natural DNA by scientific manipulation.[11] Called "cDNA"—short for "complementary DNA"—genes in such form were patentable because they were not products of nature. As a result, by the end of the 1980s, the new biotechnology industry was flourishing in the United States, energized by venture capital willing to invest heavily in firms that could patent genetically modified organisms and genes themselves. In contrast, the European Community provided no patent protection for living organisms or their genes.[12] Fearing for the competitiveness of the Community in the industrialization of molecular biology, the European Commission proposed a biotechnology directive in 1988 that would authorize the patenting of life. The European Parliament, however, was unwilling to concur in the initiative, partly on ethical grounds.[13]

II. PATENTING EXPRESSED SEQUENCE TAGS

In the 1990s, J. Craig Venter, a biologist at the National Institutes of Health ("NIH"), in Bethesda, Maryland, suddenly raised the stakes in the patenting of life by proposing the wholesale patenting of human gene fragments. Venter's lab, using automated machines, had sequenced not whole genes but random fragments of cDNA derived from part of the brain.[14] Such a fragment was called an "expressed sequence tag," or EST.[15] Although just 150 to 400 DNA coding pairs long, each

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[10] *Id.*

[11] STEPHEN HALL, INVISIBLE FRONTIERS: THE RACE TO SYNTHESIZE A HUMAN GENE (1987).

[12] David Dickson, *European Parliament Rejects Bid to Stem Confusion Over Gene Patents*, 374 NATURE 103 (1995).

[13] *Id.*

[14] Mark D. Adams et al., *Complementary DNA Sequencing: Expressed Sequence Tags and Human Genome Project*, 252 SCI. 1651, 1651 (1991); Christopher Anderson, *US Patent Application Stirs Up Gene Hunters*, 353 NATURE 485, 485 (1991).

[15] *See* authority cited *supra* note 14.

was unique and served to identify the gene of which it was a part.[16] In June 1991, Venter and NIH filed for patents on 315 ESTs and the human genes from which they came.[17]

Venter's patent ambitions seemed boundless. His lab could churn out EST sequences so quickly that NIH planned to file patent applications for 1000 of them a month.[18] At that rate, it would not be too long before he had locked up a substantial fraction of the 100,000 genes then estimated to comprise the human genome.[19] Indeed, by 1994 the number of ESTs covered by the Venter/NIH application had multiplied to almost 7,000.[20]

A number of patent experts, however, insisted that ESTs were not patentable.[21] In the United States, an invention's eligibility for a patent depends in part on it being "nonobvious" and possessing "utility," useful in some way. But the task of finding ESTs is obvious to practitioners in the field. Venter did claim that the ESTs would have utility as diagnostic probes for detecting gene expression in specific cell types and as markers for mapping the locations of genes on the chromosomes of human DNA.[22] However, his gene fragments revealed nothing about the utility of the full gene in the body—that is, its function or malfunction. He nevertheless seemed bent on using the fragments to gain control of the intellectual property in the entire gene that the EST identified. His patent strategy was comparable to claiming copyright ownership in an undescribed painting on the basis of having just a sliver of the

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[16] *See* authority cited *supra* note 14.

[17] J. Craig Venter & Mark Adams, Sequences, USPTO No. 07/716,831, at 235-36 (applied June 20, 1991).

[18] *Id.*

[19] Venter once explained himself, "I turned 21 in Vietnam. So, in that situation, I saw that there is too little time in life to waste on B.S. approaches. So, in that sense, I am impatient. I want to constantly be moving forward with the discovery of new things, and I'm frustrated with how long it takes new ideas to become part of the general thinking." Karen Young Kreeger, *Genome Investigator Craig Venter Reflects on Turbulent Past and Future Ambitions*, 9 THE SCIENTIST 1 (1995).

[20] Christopher Anderson, *NIH Drops Bid For Gene Patents*, 263 SCI., 909, 909-10 (1994).

[21] *See* Leslie Roberts, *Genome Patent Fight Erupts*, 254 SCI. 184, 185 (1991).

[22] *See* Venter & Adams, *supra* note 17.

canvas. A lawyer for the leading biotechnology firm Genentech noted, "If these things are patentable, there's going to be an enormous cDNA arms race."[23]

Venter's initiative also provoked denunciations from scientists anxious that his EST patents, if issued, would close off research by others on countless human genes. Academic biologists called EST patenting a terrible idea—"like trying to patent the periodic table," one fumed.[24] A lawyer and medical ethicist at Boston University snapped, "This is not science. This is like the gold rush."[25] James D. Watson, a Nobel laureate for his work on DNA and, at the time, head of the NIH genome project, declared cDNA patenting "outrageous"[26] and "sheer lunacy,"[27] adding that "virtually any monkey"[28] could perform this type of research. Watson argued, "What is important is interpreting the sequence. . . . If these random bits of sequences can be patented, I am horrified."[29] In April 1992, Watson resigned as head of the genome project, explaining that he was unalterably opposed to the NIH attempts to patent ESTs.[30]

A. *Response in the Biotechnology Industry and From Abroad*

The prospect of EST patenting split the biotechnology industry. The Association of Biotechnology Companies in Washington, D.C., which spoke for 280 companies and institutions, endorsed EST patenting by NIH so long as it did not favor any one company over another, for example by granting an exclusive license.[31] Still, many of the opponents of

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[23] *See* Anderson, *supra* note 14, at 485.

[24] *Id.*

[25] D'Arcy Jenish, *A Patent on Life: Scientists Seek Legal Rights to Genes*, 105 MACLEAN'S, 38-39 (1992).

[26] Anderson, *supra* note 14, at 485.

[27] Roberts, *supra* note 21, at 184.

[28] *Id.*

[29] *Id.*

[30] Michael Waldholz & Hilary Stout, *A New Debate Rages Over the Patenting of Gene Discoveries*, THE WALL ST. J., Apr. 17, 1992, at 1. Watson, however, was also under fire for conflict of interest, since he owned shares in biotech companies and refused to sell them.

[31] Rebecca S. Eisenberg, *Genes, Patents, and Product Development*, 257

EST patenting were upset by the prospect that the government—through NIH—would own those patents.[32] The Industrial Biotechnology Association ("IBA"), representing companies that accounted for eighty percent of U.S. investment in biotechnology, contended that it would be "unfair to permit the Government to exercise complete control over a product to whose development the Government contributed little."[33] Richard Godown, president of the IBA, predicted that the commercial possibilities would be clouded "if somebody spends a lot of time and money to discover the whole gene and its function, and then discovers they've got to deal with somebody who owns a patent to part of it."[34] The Pharmaceutical Manufacturers Association also opposed the NIH patent venture, declaring that "a governmental policy of ownership and licensing of gene sequences would inevitably impede the research and development of new medicines in this country."[35]

Abroad, France, Italy, and Japan announced their opposition to NIH's EST patents, fearing the patents would competitively disadvantage their budding biotechnology enterprises.[36] Echoing Watson, the French Academy of Sciences condemned "any measure which, answering purely to a logic of industrial competition, strove to obtain the legal property of genetic information data, without even having taken care to characterize the genes considered."[37] However, the British Minister of Science Alan Howarth chose to join the competition, announcing in March 1992 that the Medical Research Council would also seek cDNA patents.[38] Howarth explained that "a decision . . . not to seek patents when researchers funded by public bodies in other countries have or may do so could place the UK at a relative disadvantage."[39]

SCI. 903, 903-08 (1992); ABC Statement on NIH Patent Filing for the Human Genome Patent, Biotechnology Law Report, July-Aug. 1992, at 408-410.

[32] *Id.*

[33] *Id.*

[34] *See* Jenish, *supra* note 25, at 39.

[35] Eisenberg, *supra* note 31, at 907.

[36] Norton D. Zinder, *Patenting cDNA 1993: Efforts and Happenings*, 135 GENE 295, 295-98 (1993).

[37] ACADEMY OF SCIENCES, Paris Bilingual Report No. 32, The Patentability of the Genome (Lavoisier: Paris, 1995).

[38] Anna Maria Gillis, *The Patent Question of the Year*, 42 BIOSCIENCE 336, 336-39 (1992).

[39] *Id.*

The mounting controversy was defused when in August 1992, the U.S. Patent Office rejected the Venter/NIH claims, calling them "vague, indefinite, misdescriptive, inaccurate and incomprehensible."[40] In the agency's judgment, the patents failed to meet the standard for "nonobviousness" and the related standard of novelty.[41] NIH filed an amended patent application which was also rejected. Then, in February 1994, Harold Varmus, a Nobel laureate and the new director of NIH, announced that the agency was withdrawing its patent application on all ESTs, explaining that such patents were "not in the best interests of the public or science."[42] In Britain, the Medical Research Council quickly followed suit.[43]

B. *Venter Raises the Stakes*

The Venter/NIH application, however, had let the gene-patent genie out of the bottle, and Venter himself was of no mind to stuff it back inside. In July 1992, he had announced that he was leaving the NIH to head a new private, nonprofit research center called The Institute for Genomic Research (TIGR), to be located in Maryland near NIH.[44] TIGR received a ten-year grant of seventy million dollars from a New Jersey venture capital group called Healthcare Investment Corporation, which had already created several biotech companies.[45] The chair of Healthcare Investment Corporation, Wallace Steinberg, asserted that American scientists needed to patent genes before their European and Japanese competitors beat them to it.[46] While TIGR itself would be nonprofit, Steinberg established Human Genome Sciences Inc. ("HGS") to

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[40] Leslie Roberts, *NIH Gene Patents, Round Two*, 255 SCI. 912, 912-13 (1992); James Martinell, *USPTO, Art Unit 1805, Examiner's Action on Venter et al., Patent Application No. 07/807,195, Aug. 20, 1992*, BIOTECHNOLOGY LAW REPORT, Sept.– Oct. 1992, at 578-96.

[41] Christopher Anderson, *NIH cDNA Patent Rejected; Backers Want to Amend Law*, 359 NATURE, 263 (1992).

[42] Anderson, *supra* note 20, at 909-10.

[43] *Id.*

[44] Christopher Anderson, *Controversial NIH Genome Researcher Leaves for $70-Million Institute*, 358 NATURE 95 (1992).

[45] *Id.*

[46] *Id.*

develop and market products resulting from TIGR's research.[47] Venter took thirty NIH researchers with him and said TIGR would "do the genome project," beginning with a scaled-up continuation of his project to sequence random ESTs.[48] He predicted that TIGR would track down 1,000 genes daily and would identify the majority of human genes within three to five years.

Venter initially claimed that neither TIGR nor HGS would file patent applications for ESTs with unknown function.[49] He said he had supported the NIH patent application only because it stimulated debate and had actually hoped that the patent would not be issued.[50] A prospectus for HGS, however, indicated that the company had filed patent applications for almost 10,000 ESTs. Several other companies had also submitted EST applications, including Incyte Pharmaceuticals, Inc., which filed for protection on more than 40,000 ESTs and said that it planned to file as many as 100,000 each year.[51] The EST arms race was on.

C. *Ethical Obligations to Gene Patenting*

Ethical objections to gene patenting cropped up in Congressional hearings in 1992, but their roots went back more than a decade to the *Chakrabarty* case. During arguments in the case, vigorous objection to Chakrabarty's claim had come from the People's Business Commission ("PBC"), an activist group headed by Jeremy Rifkin.[52] Rifkin was a social agitator and sleepless critic of biotechnology. The PBC's dissent was partly economic—patents on living organisms would foster monopoly in vital areas such as the food industry. It was quasi-religious, too, holding that *"the essence of the matter"* was that

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[47] *Id.*

[48] *Id.*

[49] The Genome Project: The Ethical Issues of Gene Patenting, Hearing before the Subcomm. on Patents, Copyrights and Trademarks of the Senate Comm. on the Judiciary, 99th Cong. 102-1134 (1992) (Statement of J. Craig Venter, NIH) [hereinafter Genome Project Hearing]; Christopher Anderson, *NIH to Appeal Patent Decision*, SCI., 259, 302 (1993).

[50] Christopher Anderson, *U.S. to Seek Gene Patents in Europe*, 357 NATURE 525 (1992).

[51] Anderson, *supra* note 49, at 302; Anderson, *supra* note 42, at 910.

[52] Daniel J. Kevles, *Unholy Alliance*, THE SCIENCES (Sept./Oct. 1986) at 25-30.

to permit patents on life was to imply that "life has no 'vital' or sacred property," that it was only "an arrangement of chemicals, or mere 'compositions of matter.' "[53] In its ruling on the case, the Supreme Court majority took note of these and other apprehensions, observing that they "present a gruesome parade of horribles" and "that, at times, human ingenuity seems unable to control fully the forces it creates."[54] The majority observed, however, that genetic research with its attendant risks would likely proceed with or without patent protection for its products and that neither legislative nor judicial fiat as to patentability would "deter the scientific mind from probing into the unknown any more than Canute could command the tides."[55]

III. ETHICAL OBJECTIONS TO GENE PATENTING

With the subsequent patenting of animals, the ethical objections to the patenting of life became more charged, enlisting animal rights activists, environmentalists, and clerics.[56] Once Venter put ESTs on the patent agenda, Rifkin and his allies contended that human genes, even those fully characterized as to composition and function, should not be patented at all.[57] At Senate hearings on ethical issues in 1992, Andrew Kimbrell, the policy director and attorney for Jeremy Rifkin's Foundation on Economic Trends, the successor to the PBC, argued in favor of a moratorium on gene patenting, saying, "We are right in the middle of an ethical struggle on the ownership of the gene pool."[58] He declared that Congress should "intercede to decide where this ethical and legal free-fall ends."[59]

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[53] Brief of Amicus Curiae People's Business Commission, Diamond v. Chakrabarty, 447 U.S. 303 (1980) (No. 79-136).

[54] *Chakrabarty*, 447 U.S. at 305-18.

[55] *Id.* at 305-18.

[56] Kevles, *supra* note 8, at 65-79.

[57] Ted Peters, *Patenting Life: Yes, 63 First Things*, MONTHLY J. RELIGION & PUB. LIFE 18-20 (1996).

[58] The Genome Project: The Ethical Issues of Gene Patenting, Hearing before the Subcomm. on Patents, Copyrights and Trademarks of the Senate Comm. on the Judiciary, 99th Cong. 102-1134 (1992) [hereinafter Genome Project Hearing] (Statement by Andrew Kimbrell).

[59] *Id.*

Congress, its eye on the economic and medical potential of biotechnology, was unwilling to do anything of the sort. Patent attorneys, biotech representatives, and several congressmen warned that restrictions or a moratorium on the patenting of life or its parts would put the United States at a competitive disadvantage internationally and impede research on cures and therapies for disease.[60] Moreover, advocates of biotechnology insisted on distinguishing between issues of political economy and issues of ethics.[61] The former had a place in disputes over patent policy; the latter, at least in the United States, did not, even though they might be legitimate in principle. The appropriate venues for considering ethical issues were the legislative and regulatory arenas of government, not the Patent Office.[62]

Rifkin nevertheless maintained an ethical enfilade against gene patenting, finding allies among clerics, feminists, and whoever else might feel threatened or offended by private ownership of the gene pool. In 1995, prompted by his Foundation on Economic Trends, several prominent clerics announced at a press conference in Washington, D. C. that a coalition of 180 religious leaders representing eighty denominations had joined Rifkin's group in signing a joint appeal opposing the patenting of human genes and genetically altered animals.[63] Richard Land, President of the Christian Life Commission of the Southern Baptist Convention, declared that "the patenting of human genetic material attempts to wrest ownership from God and commodifies human biological materials and, potentially, human beings themselves."[64]

The next year, Rifkin mobilized women's rights leaders against attempts to patent genes implicated in breast cancer, claiming that such efforts represented an "assault on women" and "denies them control over the most intimate aspect of their being, their bodies' genetic blueprint."[65] He said that a coalition

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[60] Genome Project Hearing, *supra* note 58 (Statements by David Beier, Senator Pete V. Domenicia, Senator Orrin G. Hatch, and William Noonan).

[61] Genome Project Hearing, *supra* note 58 (Testimony of William D. Noonan).

[62] *Id.*

[63] Peters, *supra* note 57, at 18.

[64] Richard D. Land & C. Ben Mitchell, *Patenting Life: No*, 63 FIRST THINGS 20, 20-22 (1996).

[65] *US Coalition Counters Breast Gene Patents*, 381 NATURE 265 (1996).

would petition the Patent Office to challenge claims that had been filed on the breast cancer genes BRCA1 and BRCA2. Rifkin's statements were endorsed by members of women's health organizations in sixty-nine countries, including Betty Friedan, Gloria Steinem, and Bella Abzug, the former member of Congress and herself a breast cancer survivor.[66] Abzug averred, "Human genes are not for sale or profit. Any attempt to patent human genetic materials by individuals, scientific corporations, or other entities is unacceptable."[67]

IV. EUROPEAN COMMISSION INITIATIVES

All the while, the European Commission had continued its attempt to promulgate a biotechnology directive that the European Parliament would find acceptable. Resolution of their differences had to take ethics into account. According to article 53a of the European Patent Convention, patents that violated "public order and morality" were inadmissible.[68] Thus in Europe, unlike in the United States, by law ethical issues enjoyed a seat at the table of patent policymaking. The Commission's effort had been repeatedly blocked by ethical opposition to patenting life from members of the Green Party and their sympathizers, among others, in the European Parliament.[69]

In 1994, the Commission presented the Parliament with a new compromise draft directive that allowed the patenting of human genes provided that "they cannot be linked to a specific individual."[70] Willy Rothley, of Germany, the head of the effort to find suitable language for the directive in the Parliament, considered this provision an adequate constraint, declaring, "The European Parliament has been able to impose an ethical dimension on patent rights and has been able to obtain most of

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[66] *Id.*; Eliot Marshall, *Rifkin's Latest Target: Genetic Testing*, 272 SCI. 1094 (1996).

[67] Marshall, *supra* note 66, at 1094.

[68] Select Committee on the European Communities, Patent protection for biotechnological inventions, United Kingdom House of Lords, Session 1993-94, 4th report.

[69] David Dickson, *British MPs "Likely to Oppose Gene Patents,"* 373 NATURE 550 (1995).

[70] *Id.*

the guarantees that it was asking for."[71] However, Linda Bullard of the European Green Party, countered: "We feel that Parliament, having voted previously against patents on parts of the human body—including genes—under any circumstances, is morally obliged to reject this compromise. This is not a question of individual human dignity, but of collective human dignity."[72] The compromise directive died in March 1995, when the European Parliament voted 240 to 188 against approval, with twenty-three abstentions.[73]

But the European biotechnology industry was growing, eager to prevent the kind of ethical issues raised by Rifkin, the European Greens, and their allies that would serve to block entirely the establishment of a patent policy for biotechnological inventions. Interpharma, an association representing Swiss pharmaceutical companies, supported patents on genes or gene fragments "in a form that does not occur in nature," arguing that "isolated genes do not occur naturally, nor do large quantities of purified proteins; they should, therefore, be patentable."[74] In Germany, biotechnology had been lagging. By 1996, the political winds had shifted and the federal government began offering financial incentives to encourage German biotechnology.[75] As Maria Leptin, head of the genetics faculty at the University of Cologne, argued, "[I]f there's anything that's more important [to Germans] than saving the environment, it's saving jobs. As soon as people saw the [pharmaceutical] industry possibly disappearing, morality went out the window."[76]

In the summer of 1997, the European Parliament reconsidered the question of patenting biological inventions.[77] In the spring of 1998, it approved a wide-ranging directive on biotechnology designed to encourage patents while adopting

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[71] *Id.*

[72] *Id.*

[73] Dickson, *supra* note 12, at 103.

[74] David Dickson, *European Patent Directive in Critical Test Over Genes*, 372 NATURE 310 (1994).

[75] Steven Dickman, *Germany Joins the Biotech Race*, 274 SCI. 1454, 1454-55 (1996).

[76] *Id.*

[77] Nigel Williams, *European Parliament Backs New Biopatent Guidelines*, 277 SCI., 472 (1997); Alison Abbott, *Euro-Vote Lifts Block on Biotech Patents...But Parliament Wants Closer Scrutiny*, 388 NATURE 314, 314-15 (1997).

explicit ethical restrictions—for the first time anywhere—on what can be patented.[78] Holding that biotechnology patents must safeguard the dignity and integrity of the person, the directive prohibits patents on human parts, human embryos, and the products of human cloning.[79] The directive also prohibits patents on animals if what they suffer by being modified exceeds the benefits that the modification would yield.[80]

The ethical restrictions stopped short of limiting patents on genes and gene fragments. The directive, passed by the Parliament and formally issued by the European Commission in July 1998, authorizes patents for partial DNA sequences that are isolated from the body and for which an "industrial application"—that is, a practical use—has been disclosed. Nevertheless—again, for the first time anywhere—the directive calls for ongoing oversight of "all ethical aspects of biotechnology" by the Commission's European Group on Ethics in Science and New Technologies.[81]

V. PATENTS AND THE HUMAN GENOME

In the United States in December 1997, Jeremy Rifkin and the biologist Stewart Newman announced that, as a provocation, they would seek a patent on methods to create a human/animal hybrid, a creature part animal and part person.[82] Bruce Lehman, the U.S. Commissioner of Patents, declared that the Patent and Trademark Office would in general reject patents that were "injurious to the well-being,

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[78] Alison Abbott, *Transgenic Patents a Step Closer in Europe*, 390 NATURE 429 (1997); Alison Abbott, *Europe's Life Patent Moratorium May Go*, 393 NATURE 200 (1998).

[79] European Community, *Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998, On the Legal Protection of Biotechnological Inventions*, 213 OFFICIAL JOURNAL OF THE EUROPEAN COMMUNITIES, 13-21 (1998) [hereinafter European Community, *Directive*].

[80] For example, a mouse genetically engineered to suffer physically from birth would not be patentable if the modification did not lead to greater medical understanding, therapies, or cures.

[81] European Community, *Directive*, *supra* note 79.

[82] David Dickson, *Legal Fight Looms Over Patent Bid on Human/Animal Chimaeras*, 392 NATURE 423 (1998).

good policy or good morals of society."[83] Patent lawyers roundly attacked Lehman, contending that because United States patent law is literally amoral Lehman had no legal authority to back such a prohibition.[84] Yet even if ethics has no rightful presence in American patent policy, an ethical principle—that the human genome must not be locked up—has been creeping into the discussion through the issue of gene patenting. And nothing has done more to introduce it than the robust ambitions of Craig Venter.

In May 1998, Venter announced that he would leave the non-profit TIGR to move to a new, for-profit company, called Celera, that would be located next door, in Rockville, Maryland.[85] Celera would aim to sequence all the DNA in the human genome by 2001, using rapid new automated machines supplied by its principal owner, the Perkin-Elmer Corporation.[86] Venter declared that Celera would make all its sequence data publicly available while at the same time earn money from selling access to the information.[87] Venter's rapid-fire approach to sequencing prompted scientific critics to predict that his company's data would contain numerous serious gaps.[88] It was also unclear how the company could publish and profit from its sequence data. Early in 2000, strategies that Celera said it would follow to profit from its work appeared to threaten broad access to the sequence information.[89] Indeed, suspicion of Celera's intentions appeared to prompt President Clinton and Prime Minister Blair's declaration that information about human DNA sequences should be released into the public domain.

But Venter has revived his original goal of wholesale gene patenting. Along with several other genomic companies, Celera has proposed to use ESTs to identify new genes and

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[83] Meredith Wadman, ... *As U.S. Office Claims Right to Rule on Morality*, 393 NATURE 200 (1998).

[84] *Id.*; Dickson, *supra* note 82, at 423.

[85] Eliot Marshall & Elizabeth Pennisi, *Hubris and the Human Genome*, 280 SCIENCE 994, 994-95 (1998); J. Craig Venter et al., *Shotgun Sequencing of the Human Genome*, 280 SCIENCE 1540, 1540-42 (1998).

[86] *See* authority cited *supra* note 85.

[87] Venter, *supra* note 85, at 1541.

[88] Marshall & Pennisi, *supra* note 85, at 994-95.

[89] Eliot Marshall, *Talks of Public-Private Deal End in Acrimony*, 287 SCI. 1723, 1723-25 (2000).

guess at their function through computerized searches of the genomic data base. The company would then seek utility patents covering these genes, arguing that their functions were likely the same as those of the genes with similar structure.[90] That strategy stimulated a forceful statement in late March by Aaron Klug and Bruce Alberts, the presidents, respectively, of the Royal Society of London and the National Academy of Sciences in the United States.[91] They called guessing at gene function by computerized searches of genomic databases "a trivial matter."[92] Its outcome might satisfy "current shareholders' interests," but it did "not serve society well."[93] Holding that its results did not warrant patent protection, they stressed that "the human genome itself must be freely available to all humankind."[94]

The U.S. Patent and Trademark Office, however, flatly disagrees, judged by its current policy on the patenting of genes and DNA sequences. At the end of 1999, it invited public comments on that policy and subsequently received them from thirty-five individuals and seventeen organizations.[95] Some of the comments were ethical, echoing those of Alberts and Krug; some were legal or practical, raising objections, for example, to granting patents on DNA sequences such as ESTs by arguing that they should not be patentable because they exist in nature.[96] In January 2001, the Patent Office found reasons to refuse to incorporate any of the comments in its policies. Indeed, its responses to the comments in effect promulgated a policy governing the patentabilty of genes and DNA sequences that is enormously broad.[97]

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[90] Author's conversation with Rebecca Eisenberg, Professor of Law, University of Michigan Law School, Ann Arbor, Mich., Mar. 20, 2000.

[91] Bruce Alberts & Sir Aaron Klug, *The Human Genome Itself Must be Freely Available to All Humankind*, 404 NATURE 325 (2000).

[92] *Id.*

[93] *Id.*

[94] *Id.*

[95] Revised Utility Examination Guidelines: Request for Comments, 64 FED. REG. 71440 (Dec. 21, 1999). I am indebted to Professor Hal Edgar, Columbia University Law School, for calling my attention to this request for comments and the outcome cited below.

[96] Utility Examination Guidelines, 66 FED. REG. 1092 (Jan. 5, 2001).

[97] *Id.*

CONCLUSION

Gene patenting has exposed a conflict and, possibly, an incompatibility in patent policy between the United States and the European community. Even though the former does not impose ethical constraints on the patentability of products, the latter does, with the consequence that what may be patentable in the United States may not be so in Europe. Paradoxically, while trade barriers have been steadily falling with globalization, at least in the commerce of living organisms and their parts, patent barriers may be arising to some degree. The transatlantic mismatch aside, within both the United States and Europe, gene patenting has prompted important challenges to the scope of intellectual property rights in genes. Given that the human genome is widely regarded as a common birthright of people everywhere, governments may feel increasing pressure to limit the property rights sought in DNA sequences.